IMPLEMENTING ARRA'S HEALTH IT PROVISIONS TO SUPPORT
BETTER CARE AND OUTCOMES FOR HEALTH CARE REFORM

FOREWORD

The new law requires providers to use electronic health records, but we must be thoughtful about how our incentives work if this investment is to be transformational in the way the President and Congress envision. Will we entrench an approach that over 20 years has not yet demonstrated the potential of health IT, or will we create an environment of innovation and accountability for better outcomes?

As Presidents Bush and Obama both have said, the end goal is for all <u>Americans</u> to have an electronic health record, not all <u>American institutions</u>.

And the definition of the technology in the American Recovery and Reinvestment Act of 2009 (ARRA), reflects Congress's intent to promote health records <u>for individuals</u>:

"The term `qualified electronic health record' means <u>an electronic record of health-related information on an individual</u> that- …" New PHSA Section 3000(13) (emphasis added).

The distinction is not minor. As we are concerned with better health and care for individual Americans, this focus must be the basis of the analysis of need, design of solutions, and definition of "meaningful use".

Moreover, <u>Congress is providing incentives for *use*, not for adoption</u>. Federal regulations must reflect this significant distinction and adjust their program guidelines accordingly.

Finally, the demands on the technology will be – and *should* be – great. Congress laid out a number of goals for the creation of the National Coordinator's Office and federal investment in health IT:

> (b) Purpose. – The National Coordinator shall perform the duties under subsection (c) in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that—
>
> (1) ensures that each patient's health information is secure and protected, in accordance with applicable law;
>
> (2) improves health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient-centered medical care;

(3) reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;

(4) provides appropriate information to help guide medical decisions at the time and place of care;

(5) ensures the inclusion of meaningful public input in such development of such infrastructure;

(6) improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;

(7) improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;

(8) facilitates health and clinical research and health care quality;

(9) promotes early detection, prevention, and management of chronic diseases;

(10) promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services; and

(11) improves efforts to reduce health disparities. New PHS Section 3001.

We know that current technology generally does not deliver on these goals. Some positive results have been achieved by closed or tightly-integrated systems, but the experience has not been duplicated in interactions among unrelated organizations. Nor has it scaled well. And **even the "best" systems fall far short of our goals because of the poor capabilities of the technology and its failure to "place raw data into context with current medical knowledge to provide clinicians with computer models that depict the health status of the patient".** *See* William W. Stead and Herbert S. Lin, editors; Committee on Engaging the Computer Science Research Community in Health Care Informatics; National Research Council, *Computational Technology for Effective Health Care: Immediate Steps and Strategic Directions*, January 9, 2009, http://www.nap.edu/catalog/12572.html, accessed April 27, 2009 (The NRC Report).[1]

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[1] Despite a strong commitment to delivering quality health care, persistent problems involving medical errors and ineffective treatment

This paper begins with a discussion of the need to re-orient our emphasis with regard to electronic health records, for we have learned how crucial such an action is. From that flows a discussion regarding the functions of which the technology must be capable in order to produce the results we seek.

We then discuss what "meaningful use" of that technology should require.

Finally, although we argue that documentation of meaningful use should be as strong a link in this chain of requirements, we will restate that assertion as a placeholder – for completion when we know the requirements established for the technology and meaningful use. At the very least, the documentation should include evidence of improved care quality and outcomes as a result of the use of technology.

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continue to plague the industry. Many of these problems are the consequence of poor information and technology (IT) capabilities, and most importantly, the lack cognitive IT support. Clinicians spend a great deal of time sifting through large amounts of raw data, when, ideally, IT systems would place raw data into context with current medical knowledge to provide clinicians with computer models that depict the health status of the patient.

Computational Technology for Effective Health Care advocates re-balancing the portfolio of investments in health care IT to place a greater emphasis on providing cognitive support for health care providers, patients, and family caregivers; observing proven principles for success in designing and implementing IT; and accelerating research related to health care in the computer and social sciences and in health/biomedical informatics.

DISCUSSION

Electronic Health Records: Individual v. Institutional Records

Although the law establishes incentives for the <u>use</u> of electronic records by providers, we submit that such electronic health records must have characteristics and capabilities producing evidence of improved care and outcomes <u>for individual patients</u>. Our federal agenda has as its goal an electronic record for <u>every American</u> by 2014. Without requiring electronic records to be about *individual* patient care, we can pay for record systems in every institution without creating a record for each American.

Furthermore, we have evidence that to be most effective, the records must be usable by individuals themselves for their own care, providing the support and tools they need in the 99% of the time they are not face-to-face with the health care system, but still need to address their chronic or ongoing health care and wellness needs. It is this aspect of the deployment of these records that is responsible for a significant part of the care improvement that can be seen when properly deployed.
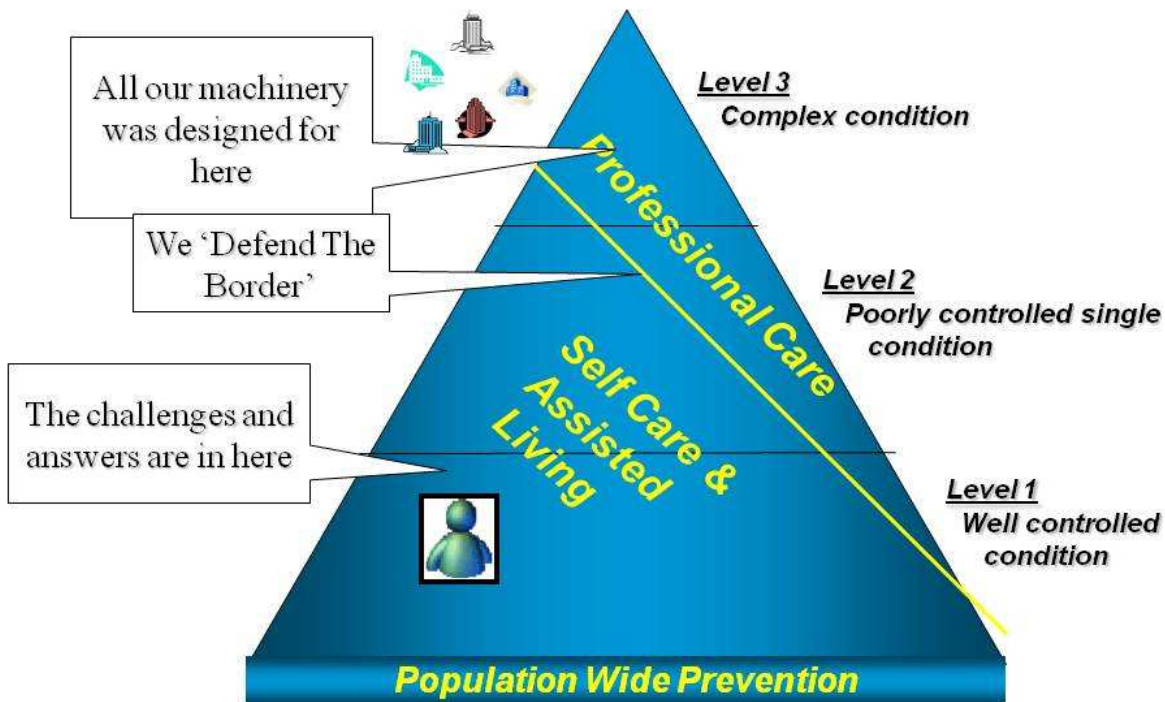
Although there are many ways to design a health information infrastructure and deploy technology, we will highlight here the most commonly advocated current approach and contrast it with the concept of records to support individual care.

In the conventional approach that has been the focus of nationwide public and private efforts for a number of years, the emphasis has been on the institution (hospital, physician practice, DM program, etc) as the point of adoption of technology, followed by integration of health information. Institutions may need this system integration to manage themselves, but this approach does *not* have as its primary goal enhanced lifelong care for individual patients. The response to this deficiency has been to encourage additional computerization of institutions – with an added requirement: connect the systems all together in an attempt to find and integrate the health care data of individual patients.

We Keep Trying to Fix the Problem by Fixing the Institutions

We try to join up a person's health experiences by joining up institutions
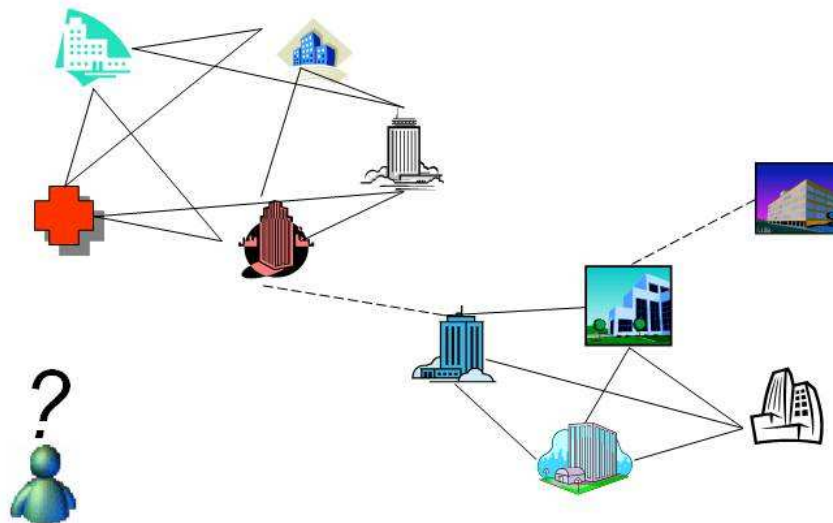
This has many drawbacks:

- it is costly

- it increases privacy and security concerns and technical complexities

- patient data items remain in multiple sites and are aggregated only on demand

  o the "record" goes away when the doctor is done with it

  o the record looks different every time it is pulled together, depending on which systems are on line, how well the record locator service works, and the quality/capabilities of the institutional system to which it is brought

  o the "record" is never complete

  o the data are never understood, they are simply combined together in a bucket for the caregiver to sort through and are about as useful to the busy clinician as a pile of faxed pages

- the permanent patient record at each institution, never designed to support a single, system-wide record on a patient, remains fragmented and incomplete

- evidence-based rules and business rules cannot operate consistently for the patient (and this is for whom they should operate *best*) because they operate separately at each institution on records that look dramatically different – this is dangerous and costly

The individual patient does not, in the end, have their own electronic health record to support their care.

As a result of these drawbacks, many physicians do not find institutional EHRs of much value for ongoing patient care, and do not trust records created by interoperable systems using record locators. For small physician practices, so little value is created that there is resistance to the investment in the technology. They can purchase an EHR, but it still doesn't tell them what they need to know about the patient from other parts of the health care system at the time they are seeing the patient. The HIE model of aggregating records does not adequately address that lack because it collects *all* of the information it finds on the patient at the time of the gathering (which still may not be complete for a number of reasons), without culling out the irrelevant data nor understanding and putting into usable form the relevant data for ongoing patient care.

It is, in fact, the long way round to trying to create electronic health records on individuals (which are inadequate anyway). This forces us to look at whether we have been advocating for the wrong thing. The assumption has been that every provider must invest in computers and we just have to link them up. Now we see that that is no different than faxing papers around. We are just automating the existing inadequate care delivery paradigm – the same paradigm we are trying to change!

The NRC report states "…**current efforts** aimed at the nationwide deployment of health care IT **will not be sufficient to achieve the vision** of 21st century health care, **and may even set back the cause if these efforts continue wholly without change** from their present course.

Specifically, success in this regard **will require greater emphasis on providing cognitive support for health care providers and for patients and family caregivers** on the part of computer science and health/biomedical informatics researchers…. This point is the central conclusion of this report." P. 2, emphasis added.

The right way round is much more direct: a straightforward record about the patient designed to support patient care.

We must create the record around the patient and let the provider community have full access to it. In this scenario, providers need only have secure internet access and permission from the patient to gain access to a complete and usable patient record that reflects the patient's data from all clinicians. The technology can also apply the privacy and security policies desired by patients to their individual records, support pay-for-performance and e-prescribing programs, and guide improved physician/patient decision-making through faster delivery of evidence-based recommendations as it evolves.

This type of record can exchange information and work with existing institutional systems. It maximally exploits the existing health care information infrastructure before we tell people to buy a whole new set of systems. Most importantly, within our reach are records that are designed to support individual health care, controlled by the individual, and not dependent on the continuing support of all institutions an individual has ever visited.

Note that we are not saying it is the only place there will be patient-related data – that would not be acceptable. Institutions can have EHR/EMRs if they benefit from them, but doctors do not need to have one to participate in the patient's care.

The difference between the two propositions is not technical – it is about the design of health care. If we are most concerned with the health care of each American, we cannot leave the support of that to ill-defined complex interactions between hundreds and thousands of systems across a super network, even if we could get it to work. We need to get what matters most into the prime position and make it central to how we design our infrastructure.

We should provide incentives and require use that bring this existing technology to benefit the care of individual patients.

Health IT & Care Management Transform Care

- The IHR integrates all clinical and financial data on a regional basis, creating a comprehensive clinical and financial record for the patient and the doctor:
- A PHR for the patient
- An E-HR and E-Prescribing for the doctor
- A data exchange infrastructure allowing health coaches and physicians to use a common record
- A rules engine with evidence-based medicine rules and benefit optimization rules loaded into the system
- In development: Health plan operational rules which will drastically reduce pre-auth for admissions, radiology services…

Designing Health IT to Serve Patients

This approach results in key infrastructure designed around the individual to answer unambiguously the most important questions:

Question	Solution
What's in my record that matters?	integrate information from all participants into a single coherent record of what matters most – create the **"single best record"**
What are we doing for my health?	integrate plans and protocols of care across all providers to operate on the individual patient's complete record

How do <u>we</u> work together?	integrate use across providers, the individual, and 'informal care providers'
Who can see and who has seen what is in my record?	integrate privacy, confidentiality, and control of use

The design for the electronic health record then follows from these requirements. <u>It provides the requirements for technology that will be effective and provide "cognitive support". One way to do this is through the creation of a single best record based optimized to manage continuing care</u>.

For this, the patient record must be more than just aggregated data. <u>The data content must be understood by the underlying technology</u> – we must understand what is in the bucket of data. (See footnote 1.) Technology exists that allows the creation of a single, comprehensive record for each patient.   Through the use of an ontology it is possible for the system itself to understand incoming data, eliminate duplicate and irrelevant data, and integrate data relevant to the diagnosis and treatment of the patient by that physician or caregiver.

Because this ontology-driven process creates only one record on which rules and protocols operate – the single best record – we can support better, more consistent clinical decision support and evidence-based care tailored to each patient.   And because the data are understandable and usable, we can create a useful presentation of the patient's record to support decision-making at the point of care.

It is this extra cognitive capability that assures the outcomes everyone seeks from health IT. With such a single consistent, system-wide and understood record on each patient, the technology can apply evidence-based quality rules, care management protocols, and business or other administrative rules in a manner unique to each patient.   Only then does each provider, and the patient, see the same comprehensive and usable record and the patient's care environment. This is of immense value to both the patient and all relevant providers of care.

The system should also have a number of capabilities (for which we already have the technical know-how) to support communication among providers and the patient, evidence-based rules, and other "cognitive support". With such capabilities, clinicians can use the system as their EHR.

An individual health record (IHR) like this is more than a PHR, or an EHR, or eRx, or clinical decision support.   As described above, it includes all of those capabilities and more. Additionally, such a "smart" technology base lays the foundation for the highly-capable, continually improving personalized system of the future, as genetic medicine and our knowledge of preventive, early intervention, and effective care management develop.

<div align="center">**RECOMMENDATIONS – QUALIFIED SYSTEMS**</div>

As Presidents Bush and Obama both have said, the end goal is for all <u>Americans</u> to have an electronic health record, not for all American institutions to have one.

Given the articulated goals of the legislation (see pp. 1-2, above) and the language around meaningful use, it is reasonable to conclude that Congress wants to promote the effective use of technology with certain capabilities. Research and experience show that most current health IT systems do not generally support those capabilities. As a result, the rules related to the technology definition in ARRA become important.

``(13) QUALIFIED ELECTRONIC HEALTH RECORD.--The term `qualified electronic health record' means an electronic record of health-related information on an individual that--

  ``(A) includes patient demographic and clinical health information, such as medical history and problem lists; and

  ``(B) has the capacity--

  ``(i) to provide clinical decision support;

  ``(ii) to support physician order entry;

  ``(iii) to capture and query information relevant to health care quality; and

  ``(iv) to exchange electronic health information with, and integrate such information from other sources."

It is clear from the legislation that what is required for electronic health records is first and foremost a record (not multiple records) "on an individual". <u>That record</u> must have the capacity to provide clinical decision support and physician order entry; capture and query information relevant to health care quality; and exchange with and integrate data from external sources.

The definition does not require that the electronic record be able to run a physician practice or hospital.[2]

Implementing regulations for the definition of `qualified electronic health record' should incorporate what we know about what works and what doesn't work:

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[2] The Department should make clear that the records for which funding is being provided are systems to support care of individuals and not necessarily systems designed primarily for running institutions or practices that have as an ancillary function the display of electronic data related to a patient held by that system. This is an important distinction and fulfills the goal of federal investment in health IT championed by President Obama.

- an electronic record "on an individual"– the technology should be capable of creating, or be part of a system capable of creating, a <u>single clinical record on individual patients designed to support the care of each such individual.</u> As the new HIPAA requirements in the bill make clear, the individual must have access to and control over this record and must have the ability to control the access of others.

- <u>that record</u> must have the capacity to provide

  - clinical decision support;

    - to do decision support competently, the technology must be able to understand and utilize relevant data from both internal and external sources in a form that (a) persists and (b) can be used in real time to execute rules, analyses and such other tools necessary to provide effective decision support;

  - physician order entry;

  - for the capture and querying of information relevant to health care quality;

    - to support improved care quality, the technology must have the same capabilities as described above for clinical decision support;

  - for exchange of patient data with and integrate data from external sources.

    - To be most effective, the regulations should require that the external information be integrated and represented to the user, and capable of understanding and use, in the same manner as the internal data

- Because access to and control over the record lies with the patient under the new HIPAA requirements, the same record can be used to support patient compliance and self-care to " (9) promote[ ] early detection, prevention, and management of chronic diseases"; – this should not depend on when or where care is provided or where the record is hosted.

- The record must be persistent. Without this requirement in regulations, privacy and security cannot be assured and the data are repudiatable.   They therefore cannot be depended on for care, undermining the quality of clinical decision support, evidence-based medicine rules, and other ancillary services.   The regulations should require that

the same single persistent record be used by the patient and all the patient's caregivers.

In addition, the regulations should make clear that payments for access to or use of such records, including access through Web technology, are eligible spending. Actual purchase of hardware or systems for managing a practice or hospital should not be a requirement and should, in fact not be considered as qualifying unless the criteria relating to the support of individual care are met.

Certification must have teeth or it becomes the weak link that can fail and reduce the potential of the technology investment. New certification categories, linked to capabilities and functions rather than site of deployment, should be developed.

Many benefits flow from this approach:

- There is more value to the patient when he/she sees the same data that the doctors see
- Privacy and security protocols can be implemented easily according to patient desires
- Errors, inconsistencies, omissions and other problems with the record are kept to a single version of the record that is accessed by all caregivers, minimizing the potential for replicating erroneous data and maximizing detection because of patient involvement and review of the data
- Patients can use their own real data and clinical instructions from their doctor or caregiver in the 99% of the time they are not in a clinical setting, at home when they need to review it
- Patient involvement results in real behavioral change based on data and guidelines specific to the patient's circumstances, improving compliance with chronic care regimens
- Patient caregivers have access to data, information, and instructions from the doctor to assist with ongoing preventive or chronic care requirements

The single, comprehensive, persistent record approach also eliminates inconsistencies across caregivers that result from their use of their own version of what the patient experience is – a version that will look different every time the record is accessed if a record locater service model is used – and that may create multiple care instructions to disparate providers because of inconsistent data or the operation of multiple clinical decision support systems that are unconnected and uncoordinated. This latter is a great threat to care quality and safety.

Another great advantage of the single record concept is that it creates communication among a patient's caregivers without each purchasing a system and joining an exchange.

RECOMMENDATIONS –"MEANINGFUL USE"

For use "in a meaningful manner", a provider should be required to demonstrate:

- regular use of a patient-centered record such as that described herein, including provision for patient access and control;
- improved care quality for individual patients through the use of accepted measures

To the extent that providers with existing EHR systems do not already have these capabilities, they must develop them no later than the end of the first reporting year.

Meaningful use should be related to the impact of health IT use on care quality and safety. It should not measure only processes. The Department should examine what clinical measures may be developed that can be best related directly to use and are susceptible to documentation requirements.

It is hard to over-emphasize the importance of this criterion. If we are confined to measuring institutional processes alone, then we shall have a misaligned system of incentives and rewards. This misalignment will result in systems that are neither useful nor usable and the IT will block rather than promote health care innovation. Experience has shown this on many occasions, with absurd consequences.[3]

Finally, we re-iterate that documentation of "meaningful use" should be as strong a link in this chain of requirements or we will not achieve the results we seek from health IT deployment.

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[3] The great danger is that an IT-based definition of "meaningful use" based on exclusively institutional measures will result in a huge bureaucratic system that requires detailed reporting of many parameters, but that has lost touch with the hoped for benefits to Americans. There is direct experience of such systems in the English NHS. For example, one measure of access/usage was every hospital specialist's desk should have on it a computer system. Institutions (hospitals etc) were set percentage targets for the specialist's desks covered. Even if one believes this makes any sense as a measure of value to patients, things soon devolve into gaming around the definition of "desk". Some places actually removed or redefined "desk" in order to raise the percentage, while others assigned multiple specialists to a single desk to achieve high figures. Meanwhile the doctors who didn't have a "desk" (because they spent their time on the wards where the patients were to be found in beds), didn't count at all in some places or unwanted desks were bought for others. And so more detailed definitions appeared, and so on and so, while nothing useful happened.